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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,987	07/14/2003	Dennis O'Brien	10745.148	5971
23862	7590	12/17/2004		
NYDEGGER & ASSOCIATES 348 OLIVE STREET SAN DIEGO, CA 92103			EXAMINER HOUSTON, ELIZABETH	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/618,987

Applicant(s)

O'BRIEN, DENNIS

Examiner

Elizabeth Houston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 14-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 01/05/2004
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. Claims 14-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected method of making, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/08/2004.
2. Claims 21-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/08/2004.
3. Applicant's election with traverse of Group 1, Species b (claims 1- 13), drawn to an anchored PTCA balloon, and shown in Figs. 9-11, in the reply filed on 11/08/2004 is acknowledged. The applicant did not point out any errors in the restriction requirement. Therefore the examiner considers the restriction requirement to be proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Abele et.al. (USPN 5,704,913). Abele teaches a system for anchoring a device to a lesion in the vasculature of a patient, which comprises: a flexible member defining an

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axis and having an inner surface and an outer surface (18), wherein the outer surface is formed with a plurality of integral protuberances seamlessly interconnected therewith to project outwardly therefrom (22, Figs 10 and 11). The protuberances are a plurality of raised ridges oriented parallel to the axis and the ridges extend radially to an edge that is also oriented parallel to the axis (Figs 10 and 11). The device has a fluid pump (26, 24, 34, Figs 5 and 6; Col. 5, line 24) for moving the member between a first configuration wherein the member is collapsed onto the axis (Col 5, line 55) and a second configuration wherein the flexible member is made substantially rigid to embed said protuberances into the lesion and anchor the device to the lesion (Col 5, line 48). The flexible member is tubular- shaped (Fig. 10) and has a first end (and a second end where flexible enclosures (30, 36) are integrally attached to each end of the member and extend away from the member in an axial direction. The first enclosure and the second enclosure, in combination with said member, establish an inflatable balloon for the system. (Figs. 1 and 11). Abele further discloses a second inflatable balloon (14) with the inner surface of the flexible member bonded (38c, Fig 10) to said balloon for movement from the first configuration to the second configuration in response to an inflation of said balloon and for movement from the second configuration to the first configuration in response to a deflation of said balloon. The system is made of polyethylene terephthalate (Col 4, line 53).

1. Claim 4 is rejected to as Product by Process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its

method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). (See MPEP § 2113) As stated above, the product is clearly anticipated by Abele and so claim 4 is unpatentable even though the prior art was made by a different process.

6. Claims 1, 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Neill et. al. (USPN 5,395,331). O'Neill teaches a system for anchoring a device to a lesion in the vasculature of a patient, which comprises a flexible member defining an axis and having an inner surface and an outer surface (Fig. 10, 302), and a means for moving said member between a first configuration wherein said member is collapsed onto the axis and a second configuration wherein said member is made substantially rigid to embed said protuberances into the lesion and anchor the device to the lesion (Fig. 1, 15). The flexible member is formed with a plurality of bumps, which are made of the same material as the flexible member and are seamlessly interconnected to, and project outwardly from the member. (Fig. 10, 304; Col.11, line 34). In the embodiment in Figs 3 and 9, the ribs are asymmetrical in fashion (Col 11, line 19). According to *The American Heritage® Dictionary of the English Language, Fourth Edition*, asymmetrical means having no balance or symmetry (a synonym or order). Therefore the ribs arranged with out balance or order and are therefore randomly arranged.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-

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7134. The examiner can normally be reached on M-Th 8:30-6:00 Alternate Fridays 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

eh


ANH TUAN T. NGUYEN
PRIMARY EXAMINER

12/17/04